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OCT 27 2011

510(k) Summary:

Submitter's Name and Address:

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Chelmsford, MA 01824-4105
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Contact Person:

Charles W. Kolifrath

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Date Summary Prepared:

August 29, 2011

Device:

RescueNet Link

Classification:

System, Network and Communication, Physiological Monitors. Product Code MSX. Device Class II.

Software, Transmission and Storage, Patient Data. Product code: NSX. Device Class: Not Classified.

Description:

The proposed RescueNet Link is a software-only product.

The ZOLL RescueNet Link system is an Emergency Medical Services (EMS) data system that electronically captures and displays patient monitoring, charting and ambulance location and navigation system data within the ambulance and communicates it for display to other locations throughout the pre-hospital and in-hospital system of care. The system is comprised of two computer hardware/software based components, MobileLink and FieldLink. Both components use general purpose, commercially available computers, networking and communications hardware combined with software supplied by ZOLL.

The MobileLink component resides within each EMS ambulance where it collects, integrates and displays patient monitoring, care reporting and ambulance location and navigation data on a large, easy to read touch screen display. Patient, care and transport data collected by MobileLink are transmitted to a central FieldLink server via cellular/internet connections. This server

provides a distribution point from which internet accessible web pages displaying the information collected within each ambulance can be viewed. The FieldLink server also provides each receiving hospital with web pages showing information about the MobileLink-equipped ambulances currently on route to the medical facility and monitoring and charting information about the patients they are transporting.

RescueNet Link is non-alarming software.

Intended Use:

The RescueNet Link system including its MobileLink and FieldLink subsystems is intended to be used for the following purposes:

MobileLink

MobileLink is intended to be used for collecting and displaying manually entered information and electronic data output by a ZOLL patient monitor/defibrillator, and by ZOLL patient charting systems and vehicle navigation systems used in EMS ambulances. The system displays information collected within the ambulance and transmits selected portions of that information via cellular/internet connections for display at central EMS headquarters and hospital emergency departments.

MobileLink is intended to be used for the wireless collection of data from ZOLL's E Series monitor/defibrillator. It is also intended to be used for collecting data (either hardwired or wirelessly) from ZOLL RescueNet ePCR electronic patient care reporting system and ZOLL RescueNet Navigator vehicle location system.

The MobileLink sub-system is further intended to store and display (on demand) treatment protocols and other documents defined by the ambulance service's Medical Director.

FieldLink

The FieldLink sub-system is intended to be used by a single EMS agency to collect patient and transport data transmitted from each of its MobileLink equipped emergency vehicles and to provide internet connected web servers that allow hospital emergency department staff to view information related to the ambulances and patients destined for their facility.

Indications For Use:

RescueNet Link is intended for use in the collection and display of data that is entered by a user (caregiver), or captured from specified medical devices or from a vehicle navigation system. RescueNet Link is indicated for use by health care providers whenever there is a need for collection and display of patient, care reporting and transport data.

Substantial Equivalence:

The features and functions of the proposed RescueNet Link are substantially equivalent to the corresponding features and functions of the Physio-Control LIFENET System (K102757, cleared for use on 11/5/2010).

Comparison of Technological Characteristics

RescueNet Link features and functions are similar to the corresponding features and functions of the indicated predicate device. Both RescueNet Link and the indicated predicate device are software-only products intended for the collection of data, including data that is entered by a user (caregiver) and data collected from other medical devices. No new issues of safety or effectiveness are raised by this premarket notification.

Performance Testing:

Extensive performance testing ensures that RescueNet Link performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications.

Conclusion

Performance testing of RescueNet Link demonstrates that its features and functions are substantially equivalent to the corresponding features and functions of the indicated commercially distributed predicate device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

ZOLL Medical Corporation
c/o Mr. Charles W. Kolifrath
Regulatory Affairs Manager
269 Mill Road
Chelmsford, MA 01824

Re: K111296
Trade/Device Name: ZOLL RescueNet Link
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiotachometer and rate alarm)
Regulatory Class: Class II (two)
Product Code: MSX, NSX
Dated: August 29, 2011
Received: August 31, 2011

Dear Mr. Kolifrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K111296

Device Name: **RescueNet Link**

Indications For Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111296